

REMARKS

Claims 28, 30-31 are in the application.

Claims 28 30-31 stand rejected under 35 USC §112, first paragraph, "because the specification while being enabling for compositions as described in the instant specification, i.e., Example 1, does not reasonably provide enablement for a composition comprising an active ingredient comprising the particular parts of ions as instantly claimed. The specification des not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims."

Claim 28 is set forth hereinbelow for ease of reference:

"Claim 28. A method for enhancing wound healing at a wound site, comprising applying to the wound site an effective amount of a therapeutic composition comprising:

a pharmaceutically acceptable carrier, and
an active ingredient of inorganic solids comprising 10-80 parts by weight of potassium ions, 0.00001-20 parts by weight of zinc ions, 0.01-10 parts by weight of calcium ions and rubidium ions in an amount of up to 40 parts by weight." (emphasis added)

The Examiner has obviously carefully reviewed the invention defined in Claim 28 and has arrived at the conclusion that "the parts by weight as recited in the claim for some of the ions cannot be achieved." This conclusion is based upon the Examiner's observation that "The claim states that the "active ingredient" is in the form of **an organic solid**. The claim further requires particular amounts of ions in **said solid**." The Examiner presents a table which is stated to be a representative example of the claimed invention". (emphasis added)

At the outset, Applicants note that Claim 28 calls for (1) "an active ingredient", (2) "of inorganic solids", (3) comprising ... (4) parts by weight of ions.

The Examiner notes that the claim states (1) "an active ingredient" (2) "of an organic solid" and (3) "the claim further requires particular amounts of ions in said solid".

The differences in the Examiner's characterization of the language of Claim 1 and the actual language of Claim 1 is of critical importance. Specifically, Claim 1 calls for "an active ingredient **of inorganic solids**". Note is to be taken of the plural word "solids". The claimed composition is made up of a plurality of inorganic solids, i.e., potassium ions, zinc ions, calcium ions and rubidium ions. Each of these ingredients is a cation and its contribution to the composition is determined on this basis, not on the basis of the weight of any counterions which may be in the composition. To use the latter method for calculation of the weight contribution of the cations to the composition would result in gross ambiguity in that there is no recitation in Claim 28 of counterions so that the possible combinations of cations and counterions are open and almost endless in that there may be many and varied multiple counterions for each of the enumerated cations. In reality, it is substantially immaterial how much weight of counterions might be in the composition in that the effective ingredients are potassium ions, zinc ions, calcium ions and rubidium ions, all within the ranges claimed, not counterions.

The Examiner is correct in her statement that the "claim further requires particular amounts of ions", but these ions are not "in said solid" as noted by the Examiner. Claim 28 does not call for a single solid, it calls for a plurality of "inorganic solids" each of which is in cationic form when its weight contribution to the overall "active ingredient" is established.

Attention is invited to the specification at page 3, (bottom portion of page) and continuing onto page 4, where it is stated:

"Thus, synthetic formulations containing, by weight of inorganic solids, 10-80 parts potassium ions, preferably 30 to 50 parts, 0.00001 to 20

parts zinc ions, preferably 1 to 10 parts, 0.01 to 10 parts calcium ions, preferably 1 to 5 parts, 0 to 40 parts rubidium ions, preferably 1 to 20 parts, and 0 to 5 parts sulfur, in the form of elemental sulfur or sulfate, TOGETHER WITH pharmaceutically acceptable counterions (e.g., Cl⁻, SO₄²⁻, CO₃²⁻, OH⁻, Br⁻). The solution may also contain OTHER INORGANIC CATIONS, for example ...". (emphasis added).

Given the language of Claim 28, and the above quoted language from the specification, it is respectfully submitted that a person skilled in the art would recognize that the weight contributions of each component (cation) of the active ingredient of the claimed composition is to be based on the cationic form of the component itself.

Withdrawal of the rejection of Claims 28 and 30-31 under 35 USC §112, first paragraph, as being not enabled is respectfully requested.

Claim 28 is newly rejected under 35 USC §112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter applicants regard as the invention. Claim 28 is stated to be "confusing because it is not absolutely clear that "parts by weight" is referring to the active ingredient or the composition as a whole.

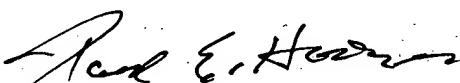
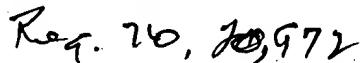
With respect to this basis for rejection of Claim 28, it is noted that Claim 28 calls for "an active ingredient" "of inorganic solids" "comprising" Then there follows an enumeration of the inorganic solids and their individual weight contributions to the "active ingredient". In Claim 28, there is no mention nor reference to the weight contribution of any other component of the active ingredient. It is respectfully submitted that this language of Claim 28 clearly calls for the "parts, by weight" of each enumerated component to be based upon the total of the weights of the enumerated components of the "active ingredient". Nonetheless, Applicant's have amended Claim 28 to recite that the parts by weight set forth for each cation are based on the total weight of the enumerated inorganic solids in their cationic form. This amendment further clarifies the basis for the term "parts by weight" and further buttresses the fact

that the "parts by weight" of the enumerated components of the "active ingredient" do not take into consideration the weight contribution(s) of any counterions which may be present in the composition.

Withdrawal of the rejection of Claim 28 under 35 USC §112, second paragraph as being indefinite is respectfully requested.

Reconsideration of the application and allowance of Claims 28 and 30-21, as amended, are requested.

Respectfully submitted,


Paul E. Hodges
Reg. 70, 10,972

March 29, 2004
Pitts & Brittan, P.C.
P.O. Box 51295
Knoxville, TN 37950-1295
(865) 584-0105 Phone
(865) 584-0104 Fax
pehodges@pitts-brittian.com